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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,484	10/21/2005	Henry Nicolas Jabbour	20747/200	4407

7590 12/19/2007

Edwin V Merkel
Nixon Peabody
Clinton Square
P O Box 31051
Rochester, NY 14603-1051

EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,484	JABBOUR ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *7-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-29 remain pending.

Applicants' election of Group VI (claim 1-7) is acknowledged. In response to the "species" election, applicants have responded that in the elected method, the AL 8810 is to be administered by itself, without a carrier, and the AL 8810 is to be administered to the female reproductive system.

Claims 1-6 are examined in this Office action; claims 7-29 are withdrawn from consideration.

✦

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is drawn to a method of "preventing" menorrhagia. However, applicants have provided no evidence that this is the case. Even if it is true that the evidence supports an assertion of enablement for "treating", it does not follow therefrom that

menorrhagia can be prevented. Suppose that, for example, the compound AL 8810 were administered to each of 10,000 women, and that over a period of time, 9,999 of them were menorrhagia-free, but that one of the 10000 women developed a mild case of the disorder. Such a result, however impressive, would actually constitute evidence that prevention had not been achieved. Perhaps enablement would exist for a method of reducing the incidence of menorrhagia (if such a method were described in the specification), but that is not what the claim recites. As matters currently stand, "undue experimentation" would be required to achieve prevention.

A matter which is somewhat separate from the foregoing concerns the term "prevents" in line 3 of claim 1 (an agent which "prevent" $PGF_{2\alpha}$ from exerting its effect"). There is no indication that any such agent exists. Perhaps applicants can find someone who has made such an assertion (regarding an agent) in a publicly available document, but applicants will be hard-pressed to find evidence that an agent exists which prevents 100% of all consequences of $PGF_{2\alpha}$ – receptor interaction. Perhaps the following would be better:

> *A method of treating menorrhagia in a female individual comprising administering to a female individual in need thereof an agent that inhibits $PGF_{2\alpha}$-mediated signalling of the FP prostaglandin receptor.*

✦

The specification is objected to. On page 6, line 17+, it is stated that uppercase letters refer to "D" amino acids, and lowercase letters refer to "L" amino acids. However, this

is the reverse of the conventional denotations; uppercase letters should refer to "L" amino acids, and lowercase letters should refer to "D" amino acids. Correction of the specification is required. Further complicating matters is that applicants have not used consistent terminology. For example, on page 12, line 8+, several sequences are listed using uppercase letters. Based on the description of page 6, line 17, one would conclude that "D" amino acids are intended (for the sequences on page 12, line 8+). However, this is not the case. As stated on page 12, line 8+, the sequences in question are disclosed in WO 01/042281. Upon review of that document, however, one finds that the sequences do not in fact consist of all "D" amino acids, as the instant specification would imply.

✦

Claims 1-6 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 makes reference to "its effect". Which effect is that?
- In claim 5, the Markush Group format is improper; the Markush Group in question contains prostaglandins and peptides. However, these two types of compounds share no core structure. The peptides should be placed in one claim, and the prostaglandins in the other. (Applicants can wait until after the final rejection to make this change, if preferred).
- In claim 5, a sequence is provided for "PCP-13.24". Within this sequence, the letter

"X" appears. This letter, however, is undefined.

- In claim 5, various sequences are provided. At this particular point in time, it is assumed that in claim 5, uppercase letters refer to "D" amino acids, and lowercase letters refer to "L" amino acids. As indicated above in the objection to the specification, this is contrary to conventional denotations. However, if applicants are going to retain this denotation, then the claim should be amended to specifically state that uppercase letters refer to "D" amino acids, and lowercase letters refer to "L" amino acids. (The best option, however, is to simply use conventional denotations).

- In claim 5, the term "PHG113" may be used if accompanied by a widely recognized chemical name. (See also the undefined terms in claim 9 such as "AH23848B" and "AH6809").

- Claim 9 is withdrawn, but there is an important matter that applicants should consider within the context of the "D *versus* L" amino acid issue. This claim makes reference to SEQ ID NO:7 (as well as to other peptides), which is the peptide "IFTSYLECL". The issue here is that the specification states (page 6, line 17+) that uppercase letters refer to "D" amino acids, and lowercase letters refer to "L" amino acids. **However**, in the sequence listing provided, there is no indication that the amino acids are of the "D" configuration (in <u>any</u> of the sequences). Thus, there is an inconsistency. Clarification or correction will be required once claim 9 is rejoined.

✧

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an

obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 2, 3 and 6 are rejected under 35 U.S.C. §103 as being unpatentable over Brown (USP 4,254,122) in view of any of the following: Farida (*Bangladesh Medical Research Council Bulletin* 7(2), 69-76, 1981) or Peplow P. V. (*Prostaglandins, Leukotrienes, and Essential Fatty Acids* 33(3), 239-252, 1988) or Robinson D. R. (*The Journal of Rheumatology. Supplement* 47, 32-39, 1997).

Brown discloses (col 7, line 19) that inhibitors of prostaglandin synthetase such as indomethacin are effective to treat menorrhagia. Each of the secondary references discloses that indomethacin is effective to inhibit the production of, or the activity of $PGF_{2\alpha}$ Thus, indomethacin is effective to mitigate the effect of $PGF_{2\alpha}$ on the FP receptor relative to the effect that would exist were the indomethacin absent. As for claim 3, the "interaction" is affected, because when indomethacin is administered, there is simply less $PGF_{2\alpha}$ available to "interact" with the FP receptor.

Thus, the claims are rendered obvious.

✧

Claims 1, 2, 3 and 6 are rejected under 35 U.S.C. §103 as being unpatentable over Tsang

(*Can J Physiol Pharmacol* 65 2081-84 1987)

Tsang discloses that mefanamic acid is effective to treat menorrhagia, and at the same time, is effective to reduce $PGF_{2\alpha}$ levels.

Thus, the claims are rendered obvious.

✦

It is suggested that applicants do one of the following: (a) cancel claims 10-13, 18, 19, 23, or (b) amend claims 10-13, 18, 19, 23 so that they recite a method of use.

Those references published in foreign languages have been stricken from the IDS. If applicants would like to have abstracts considered, the IDS should make it clear that only the abstract was considered. The following (for example) could be listed in the "other documents" section:

Abstract of JP 01199958, issued August, 1989.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER